DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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May 14, 2015

Fujifilm Medical System U.S.A., Inc.
Mary Moore
Senior Director, Regulatory Affairs and Quality Assurance
10 High Point Drive
Wayne, NJ 07470

Re: K142629
Trade/Device Name: EG-530CT, EG-530D, EC-530DL, and ES-530WE Endoscopes
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscopes and accessories
Regulatory Class: II
Product Code: FDS, FDF, FAM
Dated: April 8, 2015
Received: April 8, 2015

Dear Mary Moore,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Joyce M. Whang -S

for Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page

510(k) Number *(if known)*
K142629

Device Name

EG-530CT, EG-530D, EC-530DL, and ES-530WE Endoscopes

Indications for Use *(Describe)*

The Fujifilm Endoscopes: EG-530CT, EG-530D, EC-530DL, and ES-530WE have the following indications for use:

Indications for Use (EG-530CT):
The EG-530CT Endoscope: This device is intended for the visualization of the upper digestive tract, specifically for the observation, diagnosis, and endoscopic treatment of the esophagus, stomach, and duodenum.

Indications for Use (EG-530D):
The EG-530D Endoscope: This device is intended for the visualization of the upper digestive tract, specifically for the observation, diagnosis, and endoscopic treatment of the esophagus, stomach, and duodenum.

Indications for Use (EC-530DL):
The EC-530DL Endoscope: This device is intended for the visualization of the lower digestive tract, specifically for the observation, diagnosis, and endoscopic treatment of the rectum and large intestine.

Indications for Use (ES-530WE):
The ES-530WE Endoscope: This device is intended for the visualization of the lower digestive tract, specifically for the observation, diagnosis, and endoscopic treatment of the rectum and sigmoid colon.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) SUMMARY

FUJIFILM Medical Systems U.S.A., Inc.'s
EG-530D, EG-530CT, EC-530DL, and ES-530WE Endoscopes

Date: September 16, 2014

Submitter's Information

FUJIFILM Medical Systems U.S.A., Inc.,
Endoscopy Division
10 High Point Drive
Wayne, NJ 07470 USA
FDA Establishment Registration Number: 2431293

Contact Person:

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Identification of the Proposed Device:

Proprietary/Trade Name: Fujifilm EG-530CT, EG-530D, EC-530DL, and ES-530WE Endoscopes

Common Name: Video Endoscope
Device Class: Class II
Review Panel: Gastroenterology/Urology

Classification Information:

Classification Name	CFR Section	Product Codes
Gastroscope and Accessories (Flexible/Rigid)	21 CFR 876.1500	FDS
Colonoscope and Accessories (Flexible/Rigid)	21 CFR 876.1500	FDF
Sigmoidoscope and Accessories (Flexible/Rigid)	21 CFR 876.1500	FAM

Predicate Devices

- Fujinon Inc. G5 Gastroscopes, Model EG-450WR5 (K042043)
- Fujinon Colonoscopes, EC-530HL2 (K112391)

Intended Use / Indications for Use

The Fujifilm Endoscopes: EG-530CT, EG-530D, EC-530DL, and ES-530WE have the following indications for use:

Indications for Use (EG-530CT):

The EG-530CT Endoscope: This device is intended for the visualization of the upper digestive tract, specifically for the observation, diagnosis, and endoscopic treatment of the esophagus, stomach, and duodenum.

Indications for Use (EG-530D):

The EG-530D Endoscope: This device is intended for the visualization of the upper digestive tract, specifically for the observation, diagnosis, and endoscopic treatment of the esophagus, stomach, and duodenum.

Indications for Use (EC-530DL):

The EC-530DL Endoscope: This device is intended for the visualization of the lower digestive tract, specifically for the observation, diagnosis, and endoscopic treatment of the rectum and large intestine.

Indications for Use (ES-530WE):

The ES-530WE Endoscope: This device is intended for the visualization of the lower digestive tract, specifically for the observation, diagnosis, and endoscopic treatment of the rectum and sigmoid colon.

Technological Characteristics

Fujifilm proposed endoscopes are modified versions of previously cleared endoscopes, Fujinon G5 Gastroscope, EG-450WR5 (K042043) and Fujinon Colonoscope, EC-530HL2 (K112391).

The endoscopes are comprised of three general sections: an operation section, an insertion portion and an umbilicus. The operation section controls the angulation (up/down/left/right) of the distal end of the endoscope. The insertion portion contains glass fiber bundles, several channels and a charged couple device (CCD) image sensor. The glass fiber bundles allow light to travel through the endoscope and emit light from the tip of the insertion portion to illuminate the body cavity. This provides enough light to the CCD image sensor to capture an image and display it on the monitor. The endoscope also contains several channels to deliver air/water, provide suction, and a forceps channel. The forceps channels are used to introduce endoscope accessories such as biopsy forceps during the procedure. The umbilicus section consists of electronic components needed to operate the endoscope when plugged to the video processor and the light source.

The proposed models are used in combination with Fujifilm's video processor, light source and peripheral devices (water tank, endoscope accessories, monitor, printer, DVD recorder, electrosurgical instruments, foot switch, and cart).

The minor modifications to the endoscopes were made for the purpose of overall product enhancement and general technological advancement.

SUMMARY OF STUDIES

The subject devices have been subjected to and passed electrical safety and EMC test requirements.

Fujifilm Endoscopes, EG-530D, EG-530CT, EC-530DL, and ES-530WE were evaluated in accordance with the following safety and performance requirements in addition to the applicable quality regulations:

ANSI/AAMI ES60601-1:2005***	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
IEC60601-1-2:2007***	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic Compatibility - Requirements and tests
IEC60601-2-18:2009***	Medical electrical equipment - Part 2-18: Particular requirements for the safety of endoscopic equipment
IEC60601-1-6:2010	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
IEC62366:2007	Medical devices – Application of usability engineering to medical devices
ISO10993-1:2009*	Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process.
ISO10993-5:2009	Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity
ISO10993-10:2010	Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization.
ISO8600-1**:2013	Optics and photonics – Medical endoscopes and endotherapy devices – Part 1: General requirements
ISO8600-3 :1997	Optics and Optical instruments – Medical endoscopes and endoscopic accessories – Part 3: Determination of field of view and direction of view of endoscopes with optics
ISO8600-4:1997	Optics and Optical instruments – Medical endoscopes and certain accessories – Part 4: Determination of maximum width of insertion portion
ISO17665:2006	A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices

* Evaluation to ISO 10993-1 (Tested per ISO10993-5 and ISO10993-10) was conducted for patient contact materials.

**Evaluation to ISO8600-1 (Tested per ISO8600-3 and ISO8600-4) was conducted for medical endoscopes and accessories.

*** Evaluation to ANSI/AAMI ES60601-1, IEC60601-1-2, and IEC60601-2-18 was conducted for Fujifilm Endoscopes EG-530D, EG-530CT, EC-530DL, and ES-530WE.

The reprocessing instructions were updated and validated. Reprocessing validation was performed in conformance with AAMI TIR 30:2011 and AAMI TIR12:2010. A Reprocessing validation certificate is included with this premarket notification. Steam sterilization was validated per ISO 17665-1:2006. No clinical testing was conducted.

Substantial Equivalence

Fujifilm Endoscopes EG-530D, EG-530CT, EC-530DL, and ES-530WE are substantially equivalent to the following devices.

Proposed Device	Legally Marketed Device(s)	510(k) #
Fujifilm Endoscope EG-530D	Fujinon G5 Gastroscope, EG-450WR5	K042043
Fujifilm Endoscope EG-530CT	Fujinon G5 Gastroscope, EG-450WR5	K042043
Fujifilm Endoscope EC-530DL	Fujinon Colonoscopes, EC-530HL2	K112391
Fujifilm Endoscope ES-530WE	Fujinon Colonoscopes, EC-530HL2	K112391

The Fujifilm EG-530CT, EG-530D, EC-530DL, and ES-530WE Endoscopes are as safe and effective as the Fujinon G5 Gastroscope, EG-450WR5 (K042043) and the Fujinon Colonoscopes, EC-530HL2 (K112391). The Fujifilm EG-530CT, EG-530D, EC-530DL, and ES-530WE Endoscopes have the same intended uses and similar indications, technological characteristics, and principles of operation as the predicate devices. The minor technological differences between the Fujifilm EG-530CT, EG-530D, EC-530DL, and ES-530WE Endoscopes and the predicate devices raise no new issues of safety or effectiveness. Performance data demonstrate that the Fujifilm EG-530CT, EG-530D, EC-530DL, and ES-530WE Endoscopes are as safe and effective as the Fujinon G5 Gastroscope, EG-450WR5 (K042043) and the Fujinon Colonoscopes, EC-530HL2 (K112391). Thus, the Fujifilm EG-530CT, EG-530D, EC-530DL, and ES-530WE Endoscopes are substantially equivalent.

Conclusions

Fujifilm Endoscopes, EG-530D, EG-530CT, EC-530DL, and ES-530WE are substantially equivalent to the legally marketed devices and conform to applicable medical device safety and performance standards.